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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,736

10/11/2006

Michael V. Agrez

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9415

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EXAMINER

DUFFY, BRADLEY

ART UNIT

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1643

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,736	<b>Applicant(s)</b> AGREZ, MICHAEL V.	
	<b>Examiner</b> BRADLEY DUFFY	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 86-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 86-107 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The amendment filed May 1, 2009, is acknowledged and has been entered. Claims 88-91, 94-97, 99-103 and 106-107 have been amended. Notably, claims 88-91, 94-97, 99, 101, 103 and 107 have been amended so that they are linking claims, linking the inventions of Groups I-VIII, or strictly in the alternative Groups IX-XVIII.

2. The election with traverse filed May 1, 2009, is acknowledged and has been entered.

Applicant has elected to prosecute the invention of the Group XII, drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

Furthermore, Claims 86-91 and 93-107 are linking claims which link Groups IX-XVIII.

3. Claims 1 and 86-107 are pending in the application.

4. In view of the amendment and upon further consideration, the elected invention is additionally subject to the following election of species requirements.

### ***Election/Restrictions***

5. Restriction is required under 35 U.S.C. 121 and 372.

6. This application contains claims directed to more than one species of the generic

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invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of signal peptide are selected from the sequence of:

A. SEQ ID NO:1 or B. SEQ ID NO:3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature for the following reasons:

Each species of the invention is not linked by a special technical feature because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. For example, each signal peptide recites a different amino acid sequence and therefore each peptide has different structural elements and functions. Therefore, the species listed above, as a whole, lack a special technical feature that links the different species.

Accordingly, the different species do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

7. Applicant is required, in reply to this action, to elect a single species of signal peptide to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the

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elected species. MPEP § 809.02(a).

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of  $\beta$  integrin are selected from:

A.  $\beta$ 2, B.  $\beta$ 3, C.  $\beta$ 5 or D.  $\beta$ 6 .

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature for the following reasons:

Each species of the invention is not linked by a special technical feature because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. For example, each  $\beta$  integrin would have a different amino acid sequence and therefore each has different structural elements and functions. Therefore, the species listed above, as a whole, lack a special technical feature that links the different species.

Accordingly, the different species do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

9. Applicant is required, in reply to this action, to elect a single species of  $\beta$  integrin to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are

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generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cancer are selected from:

A. prostate, B. lymphoma, C. leukemias, D. tongue, salivary glands, gums, floor and other areas of the mouth, E. oropharynx, nasopharynx, hypopharynx and other oral cavities, F. oesophagus, G. stomach, H. duodenum, I. colon, J. rectum, K. gallbladder, L. pancreas, M. larynx, N. trachea, O. bronchus, lung, P. breast, Q. uterus, R. cervix, S. ovary, T. vagina, U. vulva, V. testes, W. penis, X. bladder, Y. kidney, Z. thyroid, AA. skin and AB. liver.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature for the following reasons:

Each species of the invention is not linked by a special technical feature because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. For example, each species or type of cancer is etiologically and pathologically distinct from the other, since, for example, each originates from a different type of tissue or cell, or manifests clinically distinct symptoms. Additionally, among many other differences; each species of cancer is associated with different risk factors; each species of cancer is associated with a different set of diagnostically useful

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molecular markers; each species of cancer differentially expresses proteins that are therapeutically useful in targeting therapeutic agents to the cancer; each species of cancer is more or less responsive to particular therapeutic agents; and each species of cancer is more or less likely to metastasize. Accordingly, each species of cancer has different structural elements and functions. Therefore, the species listed above, as a whole, lack a special technical feature that links the different species.

Accordingly, the different species do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

11. Applicant is required, in reply to this action, to elect a single species of cancer or group of cancers as listed above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

**12. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a single invention to be examined and/or an election of the species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention and the elected species of invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

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and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

### ***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding



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is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
Brad Duffy  
571-272-9935

/Stephen L. Rawlings/  
Primary Examiner, Art Unit 1643

/bd/  
Examiner, Art Unit 1643  
March 19, 2010